DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-804/S-018

SUPPLEMENT APPROVAL

Bausch & Lomb, Incorporated
Attention: Mary Harrell
Manager, Global Pharmaceutical Regulatory Affairs
7 Giralda Farms, Suite 1001
Madison, NJ 07940

Dear Ms. Harrell:

Please refer to your Supplemental New Drug Application (sNDA) dated September 15, 2010, received September 20, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zylet (loteprednol etabonate and tobramycin ophthalmic suspension) 0.5%/0.3%.

We acknowledge receipt of your amendments dated March 29, 2012, and January 18, 2013. The March 29, 2012, submission constituted a complete response to our February 24, 2012, action letter.

We also acknowledge your January 18, 2013, submission containing the corresponding user fee for this "Prior Approval" supplemental new drug application.

This "Prior Approval" supplemental new drug application provides for revisions to the Pediatric Use section of the package insert to reflect the results from Clinical Study #550 entitled, "A Clinical Safety and Efficacy Evaluation of Zylet (loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension) compared to Lotemax (loteprednol etabonate ophthalmic suspension 0.5%), Tobramycin Ophthalmic Solution USP, 0.3%, and the Vehicle for Zylet for the Treatment of Blepharoconjunctivitis in Pediatric Subjects" which was submitted in support of the determination of pediatric exclusivity, as well as for some minor editorial changes.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content

of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions regarding this supplemental application, please contact Ms. Leanna M. Kelly, Consumer Safety Officer, at (301) 796-0471. For all other inquiries regarding this NDA, call Ms. Judit Milstein, Chief, Project Management Staff, at (301) 796-0763.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

WILEY A CHAMBERS
02/06/2013